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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,940	11/06/2000	Richard M. Fike	IVGN 174.2 CON	7464

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EXAMINER	
SCHLAPKOHL, WALTER	
ART UNIT	PAPER NUMBER
1636	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/705,940	FIKE ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	mdf

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,15,16,22-27,29,32-34,36-39,41 and 44-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,15,16,22-27,29,32-34,36-39,41 and 44-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the papers filed 5/14/2007 in which claims 15-16, 22-27, 32, 44-45 were amended; and claims 28 and 31 were cancelled. Claims 1-10, 15-16, 22-27, 29, 32-34, 36-39, 41 and 44-49 are pending and under examination in the instant Office action.

Any rejection of record not recited herein is hereby WITHDRAWN.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/14/2007 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 15-16, 22-27, 29, 32-34, 36-39, 41 and 44-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Fike et al (WO 98/36051) as evidenced by the Gibco BRL Product Catalogue and Reference Guide from 1995-1996.

Note: Examiner has interpreted a dry powder medium to include agglomerated powder media because the specification teaches at page 14, lines 24-28 that "[t]he term 'dry powder' may be used interchangeably with the term 'powder;'however, 'dry powder' as used herein simply refers to the gross appearance of the granulated material and is not intended to mean that the material is completely free of complexed or agglomerated solvent unless otherwise indicated."

Fike et al teach a method for producing a dry nutritive media comprising media supplements and buffers for culturing any number of cells including mammalian cells (see entire document, especially the Abstract and page 1, lines 4-21). Fike et al teach a particularly preferred embodiment of such a method

wherein a buffer salt such as sodium bicarbonate is added to the culture medium either prior to, during or following agglomeration with an appropriate solvent, such as water, serum or a pH-adjusting agent such as an acid or base (see paragraph bridging pages 19-20). Fike et al teach that the acid or base can be added to the dry medium such that "upon reconstitution of the agglomerated medium the culture medium is at the optimal or substantially optimal pH for the cultivation of a variety of cell types" (ibid). Fike et al call such a medium an "automatically pH-adjusting medium" and teach that such a medium obviates the time-consuming and error-prone steps of adding buffer(s) to the medium after reconstitution and adjusting the pH of the medium after dissolution of the buffer(s) (see page 20, 1st full paragraph). Thus, Fike et al teach Applicant's claimed method of producing an "automatically pH-adjusting dry powder eukaryotic cell culture medium comprising (a) determining the ratio of pH-opposing buffer salts required to automatically provide a desired final pH upon reconstitution of the dry powder culture medium with a solvent comprising water; and (b) adding amounts of the pH-opposing forms of buffer salts during the production of the agglomerated powder mammalian cell culture medium in the ratio determined in step (a) to produce the medium having the desired final pH upon reconstitution. Regarding

claims 2-4, Fike et al teach such a method wherein the dry powder culture medium is packaged and sterilized using gamma rays (see page 6, 2nd full paragraph and the Abstract). With regard to claims 5-8, Fike et al teach that their methods can be used to make any number of well-known media, including RPMI-1640 and F-10 Nutrient Medium (see paragraph bridging pages 17-18). RPMI-1640 comprises $Na_2HPO_4 \cdot 7H_2O$, a dibasic phosphate buffer, as evidenced by the Gibco BRL Catalogue and Reference Guide from 1995-1996 (see page R13). F-10 Nutrient Mixture comprises a potassium phosphate salt also as evidenced by the Gibco BRL Catalogue and Reference Guide of 1995-1996 (see page R13). Regarding claim 9, Fike et al teach that the dry powder mammalian cell culture medium does not liberate CO_2 upon storage (see, e.g., Example 9 at page 52, lines 15-23). Regarding claims 46-47, Fike et al teach such a method further comprising storing the dry powder culture medium at about 0-4°C or at less then about 20-25°C (see page 30, 1st full paragraph). Regarding claim 48, Fike et al also teach such a method wherein the desired final pH upon reconstitution is about 7.1 to about 7.4 (see page 20, line 24). Regarding claim 49, Fike et al, as evidenced by the Gibco BRL Catalogue and Reference Guide of 1995-1996, teach a method of making RPMI-1640 which comprises $Na_2HPO_4 \cdot 7H_2O$, a dibasic phosphate buffer, at a concentration of

5.64 mM (1 mol/268,000 mg x 1512 mg/L = 0.00564 mol/L or 5.64 mM), falling within the claimed range of about 0.1 to about 10 mM. Regarding claims 15-16, 22-27, 41 and 44-45, Fike et al also teach methods of using the media to culture cells comprising reconstituting the media compositions of the above method in a solvent such as water and contacting cells with the solution under conditions that are favorable for growth of the cell (see page 33 lines 4-31 and page 34, lines 1-18). The cells include eukaryotic cells of many different types, including plant cells, yeast cells, mammalian cells and human cells (see page 34, lines 1-18). With regard to claims 10, 29 and 32, Fike et al also teach kits for use in the above process of culturing cells comprising the media and optionally comprising additional containers containing extracts and supplements (see, e.g., page 36, lines 14-30 and page 37, lines 1-24). With regard to claims 33-34, Fike et al teach a composition comprising the automatically pH-adjusting culture medium and at least one cell and an embodiment wherein said composition is a powder (see page 34, lines 20-27). Regarding claims 36-39, Fike et al teach such a composition wherein the cell is either a yeast cell, a plant cell, a mammalian cell or a human cell including transformed cells (see page 15, lines 22-30 and paragraph bridging pages 35-36).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 5-10, 15-16, 22, 24-27, 29, 32-33, 41 and 44-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 40 and 43-62 of copending Application No. 11/502,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims anticipate the claims of the 11/502,546 patent insofar as

Applicant has not distinguished between "agglomerated" powders and "dry" powders. Furthermore, both sets of claims are drawn to methods of making automatically pH-adjusting dry cell culture media comprising determining the appropriate ratio of pH-opposing buffer salts and adding such buffer salts to the medium. Both sets of claims are also drawn to the media produced by such a method, kits comprising such media, and methods of cultivating cells with such media.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 10 and 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27, 36, 92-95, 103 and 111 of copending Application No. 09/606,314. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims anticipate the claims of the 09/606,314 application insofar as 1) Applicant has not distinguished between "agglomerated" powders and "dry" powders; and 2) absent evidence to the contrary, the method used to produce the dry powder medium of the instant application would have all the recited properties of the claimed medium of the

09/606,314 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 10 and 29 are directed to an invention not patentably distinct from claims 27, 36, 92-95, 103 and 111 of commonly assigned Application No. 09/606,314 as set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned Application No. 09/606,314, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the

time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-

9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Joseph Woitach can be reached at (571) 272-0739.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

August 4, 2007

DAVID GUZO
PRIMARY EXAMINER